

REMARKS/ARGUMENTS

Claims 1, 2, 15, 20 and 22 are active. Claims 3-14, 16-19, 21 and 23-50 have been withdrawn from consideration.

Restriction/Election

The Applicants previously elected Group I, Claims 1-20 and 22, directed to methods for treating a disease using a ligand, and the species “peptide of SEQ ID NO: 2” (Gln His Asn Pro Arg) and “impaired social activity linked to sexuality”. The Restriction Requirement has now been made FINAL. The Applicants understand that examination will be extended to additional species upon an indication of allowability for a generic claim.

Oath/Declaration

The oath/declaration was objected to. This objection is moot in view of the attached copy of the oath/declaration.

Specification—Objection

The specification was objected to for various informalities. The first objection is moot in view of the amendments above. A Substitute Sequence Listing will be filed shortly making the required annotation changes.

Claim Objection

Claim 2 was objected to as encompassing non-elected subject matter. The Applicants respectfully request that this claim be examined to the extent that it reads on the elected species, since it is possible that additional species recited by this claim could be rejoined.

Rejection—35 U.S.C. §112, second paragraph

Claims 1, 2, 15, 20 and 22 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

These claims have been revised to drop the redundant word “peptidomimetic”.

The term “impaired social activity linked to sexuality” is defined in the specification page 14, lines 13-16, as an impairment of social relationship to a sexual partner. Please find attached a copy of a website page describing “sexual, gender identity disorders”. These are disturbances in sexual desire that cause a marked level of distress and interpersonal difficulties. Accordingly, one skilled in the psychiatric or psychological arts would readily understand the meaning of this term and know that disorders of sexual and gender identity can result in an impairment of social relationship to a sexual partner.

Rejection—35 U.S.C. §112, first paragraph

Claims 1, 2, 15, 20 and 22 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate enablement. The primary concerns are that (1) one with skill in the art would not know how to administer an SMR1 peptide (such as SEQ ID NO: 2) to treat the elected species of disorder “impaired social activity linked to sexuality”, (2) that peptidomimetics are not adequately defined or enabled, and (3) that it would involve undue experimentation to determine an appropriate route of administration for an SMR1 peptide.

With respect to an underlying indefiniteness issue, as discussed above, the Applicants submit one with skill in the psychiatric or psychological arts would understand what the term “impaired social activity linked to sexuality” means. Thus, this term is clear when read in light of the specification by one with skill in the relevant arts.

(1) Methods of using the SMR1 peptide (e.g., SEQ ID NO: 2) to treat social and sexual dysfunctions in mammals are not only described by the specification, they are extensively exemplified. The disclosure exemplifies many such behaviors, including increased interest in the environment, capacity for arousal and vocalization (page 18, lines 15-20), increased social and interpersonal activities (page 19, lines 20-22), as well as many other behaviors related to social activity and sexuality which are exemplified by the data in Examples 2-9. Examples 2 to 9 describe a panel of behaviour modifications following administration of QHNPR peptide (SEQ ID No: 2) in rats, e.g. increased interest in environment and capacity for arousal (example 2), increased behaviour of the males in the presence of females (example 3), social interaction and interpersonal activities before sexual intercourse (example 4), decreased fear of partner and increased ability to relate (example 5), loss of avoidance symptoms and enhanced willingness to enter into relationship (example 6) and prolonged social intercourse signs towards female and attention signs to personal toilet (example 7). The specification demonstrates that peptide SEQ ID No: 2 improves a panel of sexual behaviours in rat. Impaired social activity linked to sexuality is defined in the specification as the impairment of social relationship to a sexual partner (page 14, lines 13-16). Examples 3 through 7 clearly indicate that treatment of male rodents with an SMR1 peptide improves their sexual behavior.

Moreover, the use of animal models, such as rats, to model human psychological behavior has long been an integral part of medical and scientific research, see the attached Declaration/Affidavit of Dr. Renoncet-Ungeheuer. Accordingly, the Applicants respectfully request that this rejection be withdrawn as the Applicants clearly exemplify the effects of the administration of SMR1 peptides on mammalian social and sexual behavior.

(2) The term "peptidomimetic" has been deleted from the active claims mooted this issue.

(3) The Official Action also alleges that the claimed method would not be enabled for all routes of administration listed in claim 22. Clearly, the specification shows that acute venous peripheral administration is an effective route of administration for peptide SEQ ID No: 2 demonstrated in the application. It would be well within the skill of those in the medical or pharmaceutical arts to select other routes of administration. More, specifically, the Applicants disagree for the following reasons. Pettit and Gombotz (1998) disclose that problems may be encountered for administering peptides via oral route (column 4). However, their overall conclusion is that transport of peptides is feasible (sentence spanning columns 5 and 6). Furthermore, beside oral route and acute venous peripheral administration, many other routes of administration may be used by the one skilled in the art to carry out the claimed method. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. §112, first paragraph

Claims 1, 2, 15, 20 and 22 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate description. The Official Action considers that the specification fails to teach treatment of a mental disorder in humans.

The term “peptidomimetic” has been deleted from the active claims, thus mooted this ground of rejection.

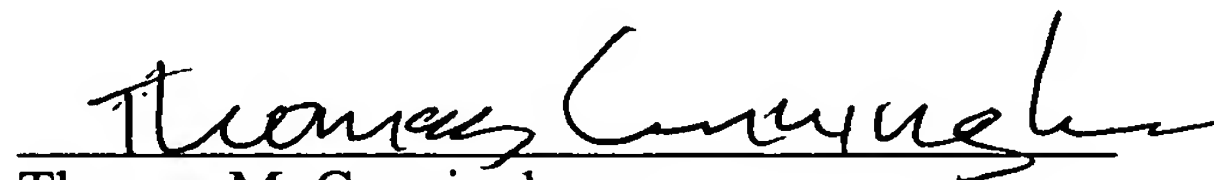
Clearly, the elected species to which examination is presently directed (impaired social activity linked to sexuality) is disclosed by page 16, line 26 of the specification and by Claim 15. Page 15, lines 5-15 and Claim 22 describe various routes of administration as well as dosages of the SMR1 peptides. Therefore there can be no issue of whether or not this subject matter is described by the disclosure. The enablement issues have been addressed above. Accordingly, the Applicants respectfully submit that this rejection may be withdrawn.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application as directed to the elected species is now in condition for allowance. Thus, extension of examination to additional species and subsequent allowance of this application is earnestly requested.

Respectfully submitted,

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